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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,832

Applicant(s)

SMITH ET AL.

Examiner

Patricia M Bianco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

*Patricia M Bianco*  
*26 Jan 2003*

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to because of the following informalities:

- Figure 9 should have an **R** with the arrow to show the direction of the rotation

OK

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "**70**" and "**71**" have both been used to designate groove (see pg. 18, lines 17-21 & 24-26). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

No

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "**124**" has been used to designate both annular wall and the region (see pg. 16, lines 25-30). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

OK/NO

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "**70**" has been used to designate both groove and latch

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arm (see pg. 18, lines 17-18). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- **280** "container" on figure 3 (see pg. 12, line 25)

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description:

- **216** on figure 1
- **208** on figure 3
- **128, 130, 132, 136** on figure 5
- **180, 181** on figure 6
- **185** on figure 7
- **128, 130, 132** on figure 9
- **180** on figure 22
- **118** on figures 25 A & B
- **232** on figure 29

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the

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Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

7. The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It appears that numerous trademarks have been recited without proper indication (such as ® or ™) after each. Clarification and proper indication of trademarks is required for the following: **PENTIUM** ™ (See pg. 7, line 30); **HYTREL**® (see pg. 12, line 2; pg. 17, line 10; pg. 24, lines 15-31); **TEFLON**® see pg. 24, line 7).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

### ***Claim Objections***

8. Claim 1 is objected to because of the following informalities: in line 7 of the claim "**including and an in-line filter**" is recited. It appears that **and** is a grammatical error and should be deleted. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giesler et al. ('708) in view of Bormann et al. (5,738,796).

Giesler et al. (hereafter Giesler) discloses a blood processing system having a blood draw tube (cell source), a separation element for separating the whole blood into its components, a pump station wherein the pump is in communication with the tubes, and a controller that controls the operation of the pump such that it operates in multiple modes. The system includes an additive solution (saline, see fig. 1 bag 50) for delivery to the cassette channel for priming. The saline is added as needed. Further, the system includes a cassette body that incorporates the tubing of the pump and blood components tubing. The pump has multiple pumping stations and valves for directing fluid flow throughout the cassette. The pump directs whole blood from the donor access to the separation element for separating wherein the components are red blood

cells and plasma. After separation of the whole blood into components, the pump directs the separated components into their respective storage containers. Giesler also teaches that a leukocyte filter may be placed in-line with the tubing to filter out leukocytes from the platelet rich plasma (PRP). The centrifuge assembly also is disclosed to include a processing controller (246) that governs the operation of the centrifuge assembly. The processing controller includes an integrated input/output terminal (248, also seen on fig. 1), which receives and display information relating to the processing procedure. The controller also governs the operation of each control station, the cassettes and the operation of the valve and pump modules to convey fluids through the cassettes to achieve the objectives of the system and treatment protocol. Giesler discloses that the controller is a processing controller that governs all of the operating functions of the system. Therefore, with respect to the controller operating the pump in alternating first and second modes to convey solutions, it would be obvious to one having skill in the art to program the controller of Giesler according to desired or optimum functions of the protocol desired since it has been held that discovering the optimum or workable ranges (i.e. modes of use) involves only routine skill in the art.



Giesler discloses the invention as claimed, however does not teach of using an in-line leukocyte filter in the component collection channel to remove leukocytes from red blood cells or where the filter is a fibrous medium in a housing.

Bormann et al. (hereafter Bormann) discloses a system and method for separating whole blood into its components and further separating leukocytes from the

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separated components in procedures such as apheresis. After separation, the separated component is passed through a leukocyte depleting filter before it is stored in its storage container. It is desirable to remove as many leukocytes from separated plasma or red blood cells since leukocytes can cause undesirable effects when administered to another patient.

It would have been obvious to one having ordinary skill in the art, at the time of the invention, to have modified the system of Giesler to include a leukocyte filter in one of the component transfer lines since it is desirable to remove as many leukocytes from separated plasma or red blood cells to prevent any undesirable effects when administering the separated plasma or cells to another patient.

### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pages et al. (5,954,971) discloses a blood processing apparatus and method including a separation device for separating whole blood into components, such as red blood cells, and wherein the separated red blood cells are passed through an in-line filter to remove leukocytes before being stored in a storage bag or container.

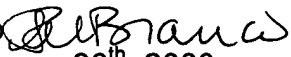
11. Any inquiry concerning the rejections contained within this communication or earlier communications should be directed to examiner Tricia Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday through Fridays, alternating Fridays off, from 9:00 AM until 6:30 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The official fax numbers for the organization where this application or proceeding is assigned is (703) 872-9302 for regular communications and for After Final communications (703) 872-9303.

Tricia Bianco  
Patent Examiner  
Art Unit 3762

tmb   
January 26<sup>th</sup>, 2003